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\*ADMITTED ONLY IN NEW YORK

May 15, 1997

### VIA HAND DELIVERY

The Honorable Roderick R. McKelvie  
United States District Court  
for the District of Delaware  
844 King Street  
Wilmington, Delaware 19801

Re: The Johns Hopkins University, et al. v. CellPro  
Civil Action No. 94-105-RRM

Dear Judge McKelvie:

We are enclosing for the Court's consideration a revised form of the proposed injunction and partial stay. For the Court's convenience, we have also included a copy of the revised form of the proposed injunction and partial stay on disk.

The changes in the proposed order relate to the stay of the injunction in the United States pending FDA approval of an alternative, noninfringing stem cell separation device. As modified, the proposed order would permit CellPro not only to supply disposable products to current users of the Cephate® SC device, but also to sell new devices and disposables to any U.S. customers, new or old, until FDA approval of an alternative therapeutic device and for a phase-down period thereafter. In addition, the stay would permit CellPro to supply infringing products to clinicians not only through the completion of currently approved clinical trials but also through the completion of any new clinical trials that are authorized up to the date the FDA approves an alternative device.

As plaintiffs previously explained to the Court, the restrictions included in the earlier draft would not, in fact, have denied patients access to stem cell technology, in view of the large number of U.S. transplant centers in which either CellPro's device or Baxter's device (or both) is already installed. However, as the Court may have observed, since March CellPro has

The Honorable Roderick R. McKelvie  
May 15, 1997  
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undertaken a massive (and irresponsible) public relations campaign designed to frighten cancer patients and their families into believing that entry of the proposed order would somehow deny them needed treatment. Plaintiffs' decision to remove the two restrictions from the proposed order is intended to allay any anxieties, however unfounded, that CellPro has created. To reiterate what plaintiffs have previously stated, it is their intention that under this order, no patient will be deprived of access to stem cell technology needed for treatment.

Respectfully submitted,



William J. Marsden, Jr.

WJMjr/kgm

PA&C/259669

CC: Clerk of the United States District Court (w/enc.) (via hand delivery)  
Coe A. Bloomberg, Esquire (w/enc.) (via facsimile delivery)  
Gerard M. O'Rourke, Esquire (w/enc.) (via hand delivery)  
Donald R. Ware, Esquire (w/enc.) (via facsimile delivery)  
Steven J. Lee, Esquire (w/enc.) (via facsimile delivery)  
Michael Sennett, Esquire (w/enc.) (via facsimile delivery)

# CERTIFICATE OF SERVICE

I, Gerard M. O'Rourke, do hereby certify that on June 5, 1997, I caused to be served a copy of the foregoing DECLARATION OF JERROLD B. REILLY AUTHENTICATING DECLARATION OF LARRY CULVER IN OPPOSITION TO PLAINTIFFS' MOTION FOR A PERMANENT INJUNCTION AND IN SUPPORT OF ALTERNATIVE MOTION FOR STAY OF INVENTION PENDING APPEAL upon the following counsel of record by the means indicated:

## BY HAND:

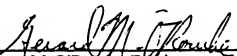
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Boston, MA 02109

  
Gerard M. O'Rourke, Esquire  
Del. I.D. Number 3265

c. From making, having made, using, selling or otherwise supplying to others, in the United States, and from importing to or exporting from the United States, the

CEPRATE LC (CD34) Laboratory Cell Separation System (the "LC34 System"), or any disposable products intended for use therewith.

d. From making, having made, using, selling or otherwise supplying to others, in the United States, and from importing to or exporting from the United States, the CEPRATE SC Stem Cell Concentrator (the "SC System"), or any disposable products intended for use therewith.

e. From making, having made, selling, supplying, importing, exporting, testing, evaluating or using for any purpose whatever, outside the United States, any hybridoma cells produced, subcloned or otherwise derived from the 12.8 hybridoma cell line, or any other hybridoma cells produced, subcloned or derived from hybridoma cells originally made in the United States.

f. From making, having made, selling, supplying, importing, exporting, testing, evaluating or using for any purpose whatever, outside the United States, any 12.8 antibodies or any other CD34 antibodies produced from hybridoma cells originally made in the United States.

g. From infringing or inducing or contributing to the infringement of any of claims 1, 2, 3, 4, 5 or 6 of the '680 patent until December 22, 2004, by making, using, selling or supplying in the United States, or importing to or exporting from the United States, any infringing suspension of human cells or by making, using or selling any product designed to produce or capable of producing an infringing suspension.

h. From infringing or inducing or contributing to the infringement of claims 1 or 4 of the '204 patent until October 23, 2007, by making, using, selling or supplying in the United States, or importing to or exporting from the United States, any infringing antibody or any infringing hybridoma, or any product which utilizes, or is designed or intended for use with, an infringing antibody.

i. For a period of two (2) years from the date of this Order, from selling or otherwise supplying to customers outside the United States, any product which utilizes or is designed or intended for use with any CD34 antibody.

(Mandatory Portions of Injunction)

IT IS FURTHER ORDERED THAT:

2. CellPro shall take immediate measures to repatriate to the United States (i) all clones or subclones of the 12.8 hybridoma cell line previously exported by it, as well as any further clones or subclones produced therefrom, including without limitation the 12.8 master cell bank hybridoma cells shipped by CellPro to Biomira, Inc.; (ii) all clones or subclones of any other CD34 antibody-producing hybridoma in its possession, custody or control, which hybridoma was first made in the United States by any person, or which, if produced from a hybridoma first made outside the United States, has been used in any way by CellPro at any time within the United States; and (iii) any CD34 antibodies that have been produced outside

the United States from any CD34 hybridomas first made in the United States, or which, if produced within the United States, are currently warehoused or stored outside the United States. CellPro shall report to the Court in writing when, and under what circumstances, such repatriation has occurred, and shall certify in writing to the Court at that time that no clones or subclones of the 12.8 hybridoma cell line, or of any other CD34 antibody-producing hybridoma cell line first made in the United States and thereafter used by CellPro, exist anywhere outside the United States, or, if it is unable to so certify, shall explain in detail the reasons for its inability to do so.

3. To the extent that CellPro has possession, custody or control of any CD34 antibodies, including but not limited to the 12.8 antibody, and any hybridoma cells capable of producing CD34 antibodies, including but not limited to the 12.8 hybridoma cell line and clones and subclones thereof, CellPro shall promptly destroy, in the presence of a United States Marshal, all such antibodies and hybridomas, and shall certify in writing to the Court at that time that it no longer has any CD34 antibodies in its possession, custody or control.

(Terms and Conditions of Partial Stay)

IT IS FURTHER ORDERED THAT:

4. The effectiveness of the above Order is hereby stayed as to the following specific activities only, and such partial stay is contingent upon CellPro's good faith compliance with the conditions set forth below:

a. CellPro may continue to make, have made, use and sell SC Systems and disposable products (including the 12.8 antibody) for use with SC Systems, within the United States, until such time as an alternative stem cell concentration device, manufactured under a license under the '204 and '680 patents, is approved for therapeutic use in the United States by the United States Food and Drug Administration (the "FDA Approval Date") and for a period of three months thereafter. During the term of such stay, CellPro shall sell such disposable products to such customers only on a bona fide as-needed basis, and shall not sell, supply or contract to supply any such customer with any quantity of disposable products in excess of such customer's anticipated short-range needs. During the three month period following FDA approval of a licensed stem cell concentration device, CellPro's total net sales of such disposable products shall not exceed 60% of its average quarterly net sales of such products during the twelve calendar months immediately preceding such FDA approval. The foregoing volume restriction shall not apply to the provision of disposable products solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date.

b. CellPro may continue to sell the 12.8 antibody from the United States, but from no other location, to its customers in the rest of the world outside the United States ("ROW") for use only with SC Systems installed at a customer location on or prior to March 12, 1997, for a period of one (1) year from the date of this Order. During the term of such stay, CellPro shall sell the 12.8 antibody and other disposable products to such customers only on a bona fide as-needed basis, and shall not sell, supply or contract to supply any such

customer with any quantity of such antibody or related disposable products in excess of such customer's anticipated short-range needs. During the first three-month period following the date of this Order, CellPro's net sales of disposable products sold for use with the SC system pursuant to this subparagraph shall not exceed its total net sales of such disposable products in the ROW during the last calendar quarter of 1996. Thereafter, such maximum permitted amount shall be reduced by an absolute 25% in each succeeding three-month period, such that in the last three months of permitted sales, CellPro's net sales of such disposable products pursuant to this subparagraph shall not exceed 25% of its total net sales of such disposable products in the ROW during the last calendar quarter of 1996.

c. CellPro may continue to make, have made, use and sell the 12.8 antibody (but no other CD34 antibody), in the United States, solely for use with the SC System in the United States or in the ROW pursuant to the terms of subparagraphs a. and b. hereof, but may not make, have made, use or sell the 12.8 antibody for any other purpose.

d. Any sales by CellPro pursuant to the terms of this partial stay shall be at prices no lower than the prices at which such products were actually sold by CellPro in the ordinary course of its business during the period January 1, 1997 to February 28, 1997 in the relevant country or region, subject to any quantity discount schedule or cash discount schedule which was actually published to customers in such country or region during that period. CellPro shall not engage in any price or other special promotions with respect to any products sold pursuant to this partial stay, nor shall it provide any customer or user with any products at no charge. The provisions of this subparagraph shall not apply to the extent the products are provided solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date.

e. Within forty-five (45) days after the close of each of calendar quarter (commencing with the quarter ending March 31, 1997), CellPro shall provide a detailed written report to plaintiffs and the Court, which shall include at least the following information:

- (1) the net sales, by number of units and dollar volume, stated separately by product code, of the disposable products sold by CellPro for use with the SC System or with any other device that utilizes CD34 antibodies in the United States during said quarter;
- (2) the net sales, by number of units and dollar volume, stated separately by product code, of the disposable products sold by CellPro sold for use with the SC System or with any other device that utilizes CD34 antibodies in or to the ROW during said quarter; and
- (3) the net sales of all SC Systems and other devices that utilize CD34 antibodies, by number of units and dollar volume, stated separately by product code and by geographic area (i.e., US or ROW), during said quarter.

f. For so long as CellPro continues to make sales in the United States pursuant to subparagraph a. above of this paragraph 4, CellPro shall pay to plaintiffs, within sixty (60) days after the close of each calendar quarter, its incremental profit on the total net U.S. revenues from such disposable products during said quarter, but not less than \$2000 per disposable product. The foregoing \$2000 floor on incremental profit per disposable product shall not apply to products provided on a so-called "cost recovery" basis solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date, and CellPro shall not be required to make any payment of incremental profit to plaintiffs in the case of disposable products that are provided solely for use in such clinical trials where the products, in their entirety, are provided to the user for no charge. The amount of incremental profit shall be determined as provided in subparagraph i. hereof, and, except as otherwise provided in the foregoing sentence, shall be payable on all such products sold or shipped on or after March 12, 1997.

g. For so long as CellPro continues to make sales in the ROW pursuant to subparagraph b. above of this paragraph 4, CellPro shall pay to plaintiffs, within sixty (60) days after the close of each calendar quarter, its incremental profit on the total net ROW revenues from such disposable products during said quarter, but not less than \$2000 per disposable product. Such incremental profit shall be determined as provided in subparagraph i. hereof, and shall be payable on all such products sold or shipped on or after March 12, 1997.

h. With respect to any SC Systems, LC34 Systems and any other devices that utilize CD34 antibodies that are sold or otherwise supplied to a customer anywhere in the world after March 12, 1997, CellPro shall, within sixty (60) days of the date hereof, pay to plaintiffs its incremental net profit on such devices. If and to the extent that any such devices were sold or otherwise supplied at a price less than the stated list price for such device in the country or region in which the customer is located, less any discount actually given pursuant to a quantity discount schedule or cash discount schedule actually published in such country or region prior to March 12, 1997, such devices shall be conclusively deemed to have been sold at the stated pre-March 12, 1997 list price for the country or region in which the customer is located, provided, however, that this sentence shall not apply to SC Systems supplied solely for use in clinical trials approved by the FDA and the applicable IRB on or before the FDA Approval Date. In all other respects, incremental profit shall be determined as provided in subparagraph i. hereof.

i. CellPro's incremental profit, as that term is used in subparagraphs f. and g. above shall be deemed to be CellPro's actual total revenues for the relevant products (net of separately-stated freight or insurance charges, permitted discounts, and returns) less its variable cost of sales, as herein defined. CellPro's variable cost of sales shall be deemed to be its variable cost of manufacture (determined in accordance with generally-accepted cost accounting practices, and adjusted for any actual manufacturing variations), plus its variable cost of distribution of such goods. Variable cost of manufacture shall not under any circumstances be calculated to include any general, administrative or overhead expenses, any research and development expenses, or any depreciation or amortization expenses. CellPro's variable cost of distribution for each quarter shall be deemed to include the following expenses only: actual sales commissions paid; a fairly allocated portion of the salary and



benefits of any salesperson devoting substantially full time to selling the relevant products; and actual freight charges not billed to the customer.

j. CellPro shall provide plaintiffs' counsel, on a quarterly basis and at the time of payment, and separately with respect to the payments required under subparagraphs f., g. and h. above, with a detailed breakdown of its calculation of its incremental profit in accordance with the above standards, and shall, on request, provide plaintiffs' counsel with supporting documents, data and written explanations. If plaintiffs disagree with CellPro's net sales reports and/or incremental profit calculations with respect to any quarter, they shall be entitled, on request, to have a firm of independent auditors examine CellPro's books and records for the purpose of determining whether such reports and calculations are fair and correct. If in any quarter CellPro is determined to have underpaid the amount due by more than five percent (5%), CellPro shall reimburse plaintiffs for the costs associated with such audit.

k. The Court intends that the limited permission granted to CellPro by the partial stay set forth in subparagraphs a., b. and c. hereof shall be strictly and narrowly construed. If there is any question as to whether a particular activity is permitted under such partial stay, CellPro shall seek approval from plaintiffs' counsel and, if necessary, clarification from the Court, before engaging in such activity.

l. Unless modified by further order, the partial stay permitted by this paragraph 4 shall terminate in accordance with the terms hereof, and without further action by the Court, and the permanent injunction shall thenceforward be in full effect.

5. The Court will retain jurisdiction of the parties and of this matter for the purpose of enforcing and/or modifying the terms of this injunction and/or the terms of the partial stay.

Dated: \_\_\_\_\_, 1997

UNITED STATES DISTRICT JUDGE